K113620

JUL 12 2012

5. 510(K) SUMMARY

[As Required by 21 CFR 807.92]
Summary of Safety and Effectiveness

Preparation date	July 13th, 2012
Submitter	
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Device name	
Common Name	System, Image Processing
Trade Name	Myrian®
Model number	N/A
Device classification	
Classification name	System, Image Processing, Radiological
Code product	LLZ
Panel	892
Regulation number	892.2050
Regulatory class	II

Predicate Devices

[K081985] Cleared [September 25, 2008] [Advantage Workstation Server], manufactured by [General Electric Healthcare];
[K061624] Cleared [June 27, 2006] [Vital Images, Inc.] [Vitrea2 Version 3.9], manufactured by [Vital Images, Inc.];
[K082228] Cleared [July 31, 2008] [Planisight Linasys] [LSPS], manufactured by [Pathfinder Therapeutics Inc.].
[K091001] Cleared [June 29, 2009] [intrasense] [Myrian v1.4], manufactured by [intrasense]
[K093621] Cleared [February 23, 2010] [syngo.PET&CT Oncology], manufactured by [Siemens Medical Solutions USA, Inc]
[K073194] Cleared [November 10, 2007] [CMRtools and plug-ins VentricularTools & ThalassaemiaTools], manufactured by [Cardiovascular Imaging Solutions, Ltd]

Explanation of how the device operates

Myrian® with its modules is designed to run on standard PC hardware, through the installed operating system. The hardware is all "off-the-shelf' standard computer components and may be purchased independently by the end user.
The exact same version of the Myrian® application can be installed on an Application Server Platform and executed in "Remote Execution Mode" (REM). In REM mode, multiple Users can remotely access all Myrian® features from any Client Platform (off-the shelf computers, including laptops), through a LAN or WAN network. This access is granted through a Web browser (via a standard URL) or a specific Client Application installed on the Client Platform

IFU (Indications For Use)

Myrian® is a software medical device aimed at reviewing images produced by all standard medical imaging devices. It also includes DICOM communication, media interchange (printing, CD burning, storing) and reporting features. Myrian® can be run from any standard client platform (such as PC) that might be purchased independently by the end user.
Common Users are trained medical professionals, including surgeons, radiologists, clinicians and technicians.
This device is not indicated for mammography use. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

Intended Use

Myrian® is a medical image review and aided diagnosis software. It is a Software Medical Device as defined by the 93/42/EEC Directive. It provides Users with the following features:
Import and export of DICOM files from/to any DICOM-compliant modality, workstation or PACS.
Visualization of DICOM images in various standard visualization modes (e.g. MPR, 3D...etc.) with optional image-alignment feature;
Creation of Objects Of Interest ("OOI") for analysis and measurement purposes;
Generation of medical reports;
Virtual Cutting surface tool for preoperative evaluation of surgery strategies;
Longitudinal Follow-up of patient, designed to support the oncological workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of such lesions.
Common Users are trained medical professionals, including surgeons, radiologists, clinicians and technicians.
Myrian® is designed to be run:
On standard Standalone Platform, through the installed operating system. The hardware of such platform consists in "off-the-shelf' standard PC computer components and may be purchased independently by the end user.
Remotely, through a network connecting a Client Platform (standard desktop or laptop PC, Apple® Mac, etc.) to the Server Platform on which Myrian® is installed. This mode of usage of the Myrian® application is called "Remote Execution Mode".

Device Description

Myrian® includes toolsets which enable the reviewing physician to provide any selected relevant information for diagnosis, surgery and treatment planning to the referring physician.
These toolsets are categorized as follow:
Imaging tools:

- Multi-Planar Reformatting views (MPR) in orthogonal, oblique or curved planes as well as 3D Views in various rendering modes including MIP, MiniP, Average and Volume Rendering
- Cross-sectional or Endoscopic Exploration Modes along a Centerline, e.g. of a vessel, a colon, etc.
- "Filet Visualization Mode", to visualize any tubular, hollow organ, such as a colon, as a flat, unfolded surface

Manual or interactive Objects Of Interest (OOI):

- Annotations of Interest (AOI), for information or measurement purposes
- Paths (considered as Annotations of Interest)
- Regions of Interest (ROI), for anatomical and pathological structure isolation (such as liver, spleen, lungs, colon ...etc.) through which any measurement can be performed
- Points of Interest (POI), for marking areas such as lesions, etc.

Reporting tools:

- Objects of Interest (OOI) generate Reports which may be viewed and exported to standard film and paper printers or sent electronically to intranet web servers and any DICOM device.

Manual or assisted image alignment tools for multiphase or time-based image comparison.
Virtual ROI Cutting Surface tool for preoperative evaluation of surgery strategies, e.g. for a liver
Longitudinal Follow-up tools for oncology workflow:

- A dedicated workflow and user interface, including a way to organize images in "Time Points", every Time Point being a subset of Studies selected by the User;
- A set of measurements collected by the User in each Time Point through the abovementioned Objects of Interest
- A mechanism to link together these Objects of Interest through the Time Point, called "Lesion of Interest";
- Some Follow-up Response Evaluation Criteria (one per Longitudinal Follow-up, e.g. RECIST 1.1 or Cheson 2007) attached to the Lesions of Interest;
- An Automatic or Semi-automatic Response Calculation using the attached Follow-up Response Evaluation Criteria, used to quantify the analysis. This Calculation is based on the strict implementation of the related reference publications (e.g. http://www.eortc.be/recist/documents/RECISTGuidelines.pdf for RECIST 1.1), and can be controlled and overridden by the User;
- A validation mechanism to sign and lock every analyzed Time Point used in the Longitudinal Follow-up;
- Specific Reports based on the chosen Follow-up Response Evaluation Criteria.
- Multiple Longitudinal Follow-ups per Patient.

All Myrian® functionalities can be packaged, licensed and marketed as individual modules:

XP Lung:

Myrian® XP Lung is designed to study the human respiratory system to help clinicians identify and analyse lung pathologies such as emphysema
The XP-Lung Module Engine makes use of a set of dedicated tools such as:

- Dedicated generic Protocols to predefine the workspace and available tools
- A semi-automatic Lung ROI segmentation engine
- The CutSimulator tool to simulate surgical action

Used in conjunction with other tools in Myrian® such as the density histogram, it is possible to visualise, analyse and quantify healthy and pathological lung tissues rapidly with precision as well as to plan and simulate excision or lobectomy

XPLungnodule:

Myrian® XP LungNodule enables volumetric analysis and follow-up of lung nodules making use of such functionalities as:

- Automatic segmentation and volumetric analysis of solitary solid lung nodules
- Automatic measurement and characterization as well as 3D visualisation of the nodules in their context
- Matching and follow-up tools
- Density Histogram
- Auto-adjusting display protocols, optimising the workspace and available tools
- Advanced Surfacic mode rendering
- Dedicated report template

XP Liver:

Myrian® XP Liver is designed for use on CT datasets with contrast enhancement for portal veins and slices below 2 millimetres in thickness.
The available dedicated tools and features include the automatic segmentation, the measurements and analysis of liver structures as well as 2d/3d hepatectomy simulation enabling to plan single phase and multiphase Liver surgery.

XP Vessel:

Myrian® XP Vessel is designed for the visualisation and analysis of medical image data derived from CT, MRI scans of selected human vessels, including but not limited to the coronary arteries, the carotid arteries, the peripheral arteries, the aorta, arteries of the brain, and any opacified veins.

The aim is to help automate routine inspection of human vessels to detect stenosis, aneurismal sac and dissection in the vessel. It also supports the interactive segmentation of any vessel and enables the isolation of, highlighting or hiding of certain parts of the data set from display for critical evaluation of selected part(s) of vessel. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, measure, evaluate, archive, print and distribute DICOM compliant vessel image studies.

XL Onco:

Myrian® XL-Onco is designed around 3 methods enabling the analysis and review of various types of lesions of interest. Each method comprises three stages (baseline, time point and validation stage creation) and has its specific constraints according to the corresponding guidelines (RECIST 1.0, RECIST1.1 and CHESON).
The use of the following enhanced features allows you to detect, assess and ensure accurate volumetric longitudinal follow-up of the lesions:

- Automatic segmentation engine
- Editing tools
- Viewport layout enabling to compare one time point to the other
- Follow-up dashboard including lesion graph and table.

The Myrian® System allows OEM customization of both the Graphical User Interface (GUI) and the available functionalities without implying any impact on system performance or system intended use.
This device is not indicated for mammography use. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.
An identical version of this software can be installed on an Application Server Platform and executed in "Remote Execution Mode" (REM). In REM mode, multiple Users can remotely access all Myrian® features from any Client Platform (off-the shelf computers including laptops), through a LAN or WAN network. This access is granted through a Web browser (via a standard URL) or through a specific Client Application installed on the Client Platform.
Medical Images themselves are not transmitted. Instead, during User interaction, a stream of screen content which is compressed using either a lossless or lossy compression scheme, is transmitted from the Application Server to the Client Platform.
Access to Myrian® REM and the stream of screen content are both encrypted to ensure security and confidentiality.
For diagnostic purposes, the User must make sure that the compression scheme and the Client Platform display device used for reading the images both comply with state-of-the-art diagnostic requirements and all current legislation, rules and regulations in force.
Once accessed in REM mode, Myrian® is intended to be used exactly as the Myrian® Medical Device.

Performance data

The performance and safety of Myrian® is evaluated in pre-marketing phase during the production cycle through verification and validation including the internal performance evaluations.
Before release of the software following testing are performed to check that the device meets the defined specifications and fullfils its intended use:

- Pre-integration testing assures that all modules aimed at being integrated into the system behave consistently before integration to the system.
- Functional Testing ensures that each element of the application meets the functional requirements of the business as outlined in the System Requirement Specification (SRS) and in the System Functional Sheet
- Integration Testing proves that all areas of the system interface with each other correctly and that there are no gaps in the data flow. Final Integration Test proves that system works as integrated unit when all the fixes are complete.
- Regression Testing ensures that there is no impact on previously released software. The regression testing is automated using ISVCR Automated Testing Tool.
- Build Testing is to be performed by the Build Engineer: no warning or compilation error should appear and binaries should be silently produces.

Tests are performed by referring to a Test Plan which contains all test procedures created to guaranty that all the functional and operational aspects of the software are under control. The tests runs were successfully completed and were documented in the Software.

Internal performance evaluations are performed to check that the software fulfills its intended aim particularly for the clinical applications with complete safety for the patient.
Clinical features refer to functionality which:
- is closely related to patient risk

and/or - *is intended to be used for diagnosis purpose*

Typically it refers to segmentation engines.

According to the intended use of the feature the methodology and the statistical analysis to apply is defined. Sample size and relevant inclusion criteria are specified in order to select the appropriate exams.

The performance and safety of Myrian® is also evaluated in post-marketing phase though a literature review. This review is performed for every considered paper evaluated as suitable to demonstrate the performances and/or safety of Myrian®. Every such document is analyzed to ensure that all identified risks are already covered and no new risk is identified. The literature review demonstrates Myrian's capability to be used in clinical environment as intended by the manufacturer.

Based on this evidence Myrian® achieves its intended performance during normal conditions of use. Known and foreseeable risks and any adverse events are minimized and acceptable when weighed against the benefits of the intended performance.

Technological characteristics

Myrian® is a multi modality medical diagnostic device for the review and analysis of anatomy and pathology in multi-dimensional digital images acquired from a variety of imaging devices. Myrian® provides users with several visualization modes and includes DICOM communication, media interchange (printing, CD burning, storing). This intended use is substantially equivalent to the one of the predicate devices Advantage Workstation Server® (K081985) and Vitrea2® (K061624).

Myrian® provides user with annotations, measurement, quantification and reporting tools. These features are substantially equivalent to those of the predicate device Vitrea2® (K061624).Myrian® contains an Endoscopic exploration mode to visualize any tubular hollow organ such as colon. This feature is substantially equivalent to the one of the predicate device Vitrea2® (K061624).

Myrian® includes toolsets which enable the reviewing physician to provide any selected relevant information for diagnosis, surgery and treatment planning to the referring physician. These features are subtantially equivalent to those of the predicate device Planisight Linasys™ (K082228).

Myrian® provides users with longitudinal follow-up tools for oncology workflow. These features are substantially equivalent to those of the predicate device syngo.PET&CT Oncology (K093621).

The Iron Load Calculator available in Myrian® is substantial equivalent to the Thalassaemiatools included in the predicate device CMRtools (K073194), and which allows the calculation of a property called T2 that characterizes iron loading in the liver.

Myrian® can be installed on an Application Server Platform and executed in "Remote Execution Mode". This mode of operation is substantially equivalent to the one of the predicate device Advantage Workstation Server® (K081985).

Conclusion

The 510(k) Pre-market Notification for Myrian® contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate devices listed above.
Myrian® has the same indication for use and does not raise any new type of safety and effectiveness questions. Performance data provided demonstrate that the device is safe, effective, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Frederic Banegas
CTO
Intrasense
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MONPELLIER 34000
FRANCE

JUL 12 2012

Re: K113620
Trade/Device Name: MYRIAN 1.11
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 2, 2012
Received: July 10, 2012

Dear Mr. Banegas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113620

Device Name: MYRIAN 1.11

Indications for Use:

Myrian® is a software medical device aimed at reviewing images produced by all standard medical imaging devices. It also includes DICOM communication, media interchange (printing, CD burning, storing) and reporting features. Myrian® can be run from any standard client platform (such as PC) that might be purchased independently by the end user.
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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113620